



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/702,303

11/06/2003

Arnold R. Leiboff

461.1008

8007

22846

7590

02/19/2008

BRIAN ROFFE, ESQ

11 SUNRISE PLAZA, SUITE 303

VALLEY STREAM, NY 11580-6111

EXAMINER

HALL, DEANNA K

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

02/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/702,303	Applicant(s) LEIBOFF, ARNOLD R.	
	Examiner DEANNA K. HALL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgments

1. This office action is in response to the reply filed on November 26, 2007.
2. In the reply, the applicant amended claims 1, 3, 7-15, 20, 23 and 25 and added new claims 29-30. Claims 1-30 are pending in the application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claims 1-3, 7-20, 23-25 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leiboff (US 4,637,814) in view of Majlessi (US 4,842,583).**

Leiboff discloses an elongate, resilient shaft 34 with a spherical bulbous enlargement Fig. 2 having a smooth, arcuate outer surface arranged at the distal end. Leiboff teaches pushing the shaft having a bulbous enlargement into a body cavity and sliding an irrigating tube over or along the guidewire or passing the shaft 34 having the bulbous enlargement in an interior of or along the irrigating tube (catheter) 22a, C21

Art Unit: 3767

L41-45. It is examiner's position that either of these types of guidance are well known in the art.

Leiboff further discloses the irrigating tube 22a having a distal end, a passage and an opening at or near the distal end which communicates with the passage Fig. 6 and directing fluid 49 through the passage to irrigate the body cavity.

Leiboff further discloses adding inflatable balloons to the distal end of the tube to enable the surgeon to obtain a good grip on the tube to more easily manipulate it through the bowel C21 L48-56. With like idea, it would be obvious to a person skilled in the art at the time the invention was made to have modified the device (the obturator) of Leiboff with the tube of Majlessi for easily grasping the spherical bulbous enlargement 26 that is about 0.25 inches (or from about 0.25 inches to about 0.75 inches) C3 L54-61, C4 L7-14.

Majlessi further teaches guiding the guidewire through the body cavity by manipulating (grasping) the bulbous enlargement and pulling the guidewire outward from the body cavity to compress and shorten the distance between an entrance to the body cavity and a treatment site C3 L54-61.

Leiboff further discloses the body cavity being the colon and the bulbous enlargement having a smooth arcuate surface as to not cause perforation of the wall of the body cavity C4 L12-18.

5. Claims 4-6, 21-22 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leiboff in view of Majlessi further in view of Stevens (US 4,811,743).

The combination of Leiboff and Majlessi discloses the invention as substantially claimed (see above). However, even though both Leiboff C21 L41-45 and Majlessi C2 L27-29 discuss guiding devices that are inherently flexible, they do not directly disclose the structure of the guide shaft.

Stevens, in the analogous art, teaches that the portion of the shaft attached to the bulbous enlargement is more flexible than the remainder of the shaft C3 L9-10; a tapered shaft, C3 L63-64, Fig. 4; and a shaft comprising a central metal wire 24 surrounded by a coil 26, Fig. 2. Stevens, being used as a guide, meets the "field of endeavor test" for analogous art as determined by 381 F.3d at 1326, 72 USPQ2d at 1212. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the combination of Leiboff/Majlessi with the shaft of Stevens for guiding the irrigation tube in the body.

Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deanna K. Hall/
Examiner, Art Unit 3767

/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767